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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,351	01/31/2001	Daniel H. Maes	00.22US	5974

7590

11/05/2002

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EXAMINER

WILLIS, MICHAEL A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 11/05/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/773,351

Applicant(s)

MAES ET AL.

Examiner

Michael A. Willis

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any previous rejections that are not restated in this Office Action are hereby withdrawn. Applicant's arguments are considered as they apply to the new grounds of rejection.

Request for Continued Examination (RCE)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment filed on 1 October 2002 is entered. Claims 1, 13, 16, and 19 are amended. Claims 1-20 are pending.

The following new grounds of rejection are made:

Claim Rejections - 35 USC § 112

Claims 1-12 and 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected due to the phrase "effective amounts". As the desired effect is not stated in the claim, it is unclear what amount is required to meet the limitation of an

effective amount, and one of ordinary skill in the art would not be apprised of the scope of the claim.

Claims 16 and 19 are rejected for being confusing due to the phrase "and applying said mixture to the skin". It is unclear if the phrase refers to the mixture of cholesterol sulfate or salts thereof and an amino sugar, or whether the phrase refers to the combination of the mixture and the vehicle, since the mixture of cholesterol sulfate and amino sugar are previously added to the vehicle in the earlier part of the claims. *maintain*

Claim 18 is rejected for lack of antecedent basis for the claimed range of "about 0.04 to about 1.0 percent". The lower limit of about 0.04 is outside the lower limit of about 0.05 in claim 16 from which claim 18 depends. The rejection can be overcome by amending claim 18 to be in agreement with claim 16.

Any remaining claims are rejected for depending from an indefinite base claim.

Claim Rejections - 35 USC § 102

Claims 1, 3, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribier et al (US Pat. 5,925,364). Ribier '364 discloses compositions comprising alkali metal salts of cholesteryl sulphate and keratolytic agents (see claim 1, col. 13, lines 50-55 and claim 15, col. 14, lines 43-54). The claimed exfoliant of the instant application encompasses keratolytic agents, particularly agents such as retinol and salicylic acid (see Ribier '364, claim 18, col. 15, lines 1-12) which are known exfoliants. Extract of centella asiatica is disclosed (see claim 18, col. 15, line 8). While the disclosure of Ribier '364 discloses a number of compositions, the rejection does not require "picking

and choosing" as the disclosed compositions are contained in the claims. Applicant's arguments regarding the distinction between mixing components and encapsulating components are addressed below.

Claim Rejections - 35 USC § 103

Claims 1-9, and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al (US Pat. 5,650,166).

The instant invention is drawn to compositions comprising cholesterol sulfate or salts thereof, an exfoliant, and a vehicle. A claimed cholesterol sulfate salt is the potassium salt. A claimed exfoliant is N-acetylglucosamine. The compositions further comprise cholesterol and/or linoleic acid. Additional claims are drawn to methods for improving or maintaining a healthy skin barrier, and methods for treating or reducing damage to the skin.

Ribier '166 teaches moisturizing compositions for the treatment of surface and deep layers of the skin. The compositions are comprised of dispersions of lipid vesicles containing active ingredients. Ribier '166 teaches the use of cholesterol sulfate as a component of the lipid membrane of the vesicles (see col. 3, line 57 through col. 4, line 2). Ribier '166 further teaches the use of sugars as the active ingredients, including N-acetylglucosamine (see col. 5, lines 59-67). Fatty acids, including linoleic acid (see col. 6, lines 44-46) are taught. Cholesterol is also taught as an active ingredient (see col. 6, lines 47-49). Ribier' 166 further teaches the use of plant extracts (see col. 7, lines 5-8). Treatment of the skin with respect to moisturization and loss of moisture to the

environment are taught (see col. 1, line 7 through col. 2, line 30). It is the position of the examiner that a method to moisturize the skin with the composition as taught by Ribier '166 inherently improves the healthy skin barrier. The reference lacks examples comprising the taught ingredients as well as weight percentages as claimed.

While the reference lacks examples comprising the taught ingredients, it would be obvious to formulate compositions with the ingredients taught by Ribier '166 in order to benefit from the moisturizing properties of the compositions taught by Ribier '166. Additionally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Applicant's arguments with respect to previous rejections are considered as follows. Applicant argues that there is no support provided to indicate why or how one of ordinary skill in the art would understand that a mixture of the present invention is taught or suggested by a lipid vesicle described in the '166 reference. Applicant suggests that the "mixture" of the instant claims is equivalent to a randomly oriented combination, and therefore does not overlap with compositions comprising lipid vesicles. In response, the feature upon which Applicant relies, namely a randomly oriented combination, is not recited in the instant claims. The term "mixture" is read broadly, and therefore includes both ordered and random compositions. In order for Applicant's argument to be

convincing, the claims must be amended such that the claims do not read on vesicle compositions, assuming support for such an amendment exists in the specification.

Applicant further argues that the addition of the components to a cosmetically or pharmaceutically acceptable vehicle as claimed distinguishes the claimed compositions from Ribier '166 in that Ribier '166 only discloses the use of these ingredients to form vesicles. Applicant asserts that a component that is first encapsulated by a vesicle before being added to a vehicle does not meet the limitation of being added directly to a vehicle. Applicant's argument is not convincing in that Ribier '166 teaches the formation of a moisturizing cream by the addition of the vesicles to aqueous and fatty phases (see Example 1, col. 8, line 50 through col. 9, line 15). The feature upon which Applicant relies, namely the direct addition of a component to a vehicle without any previous encapsulation steps, is not recited in the claims. The term "added" is read broadly to include any variety of mixing steps.

Finally, Applicant argues that Example 1 of the instant application shows unexpected results. The Example compares the skin barrier condition of skin treated with a composition containing 29 different ingredients versus untreated skin. Applicant argues that the additional 27 ingredients have no bearing on the results, in that 2/3 of the ingredients are commonly found in cosmetic vehicles, and the remaining 8 ingredients are preferred embodiments of naturally occurring skin barrier components. As stated previously, the Examiner cannot make any meaningful conclusions with respect to treating the skin barrier function of skin by the combined activity of 2 ingredients out of a total of 29 ingredients when the comparison is made versus

untreated skin, particularly where so many of the ingredients are naturally occurring skin barrier components.

Claims 10-12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier '166 as applied to claims 1-9 and 13-19 above, and further in view of Subbiah (US Pat. 6,150,381) and Ichinose et al (US Pat. 5,702,691).

The claims are directed to compositions further comprising sclareolide and white birch extract.

See above for a discussion of Ribier '166. While the reference teaches the generic use of plant extracts (see col. 7, lines 5-8), the reference lacks sclareolide and white birch extract.

Subbiah teaches the use of sclareolide in topical formulations, particularly for acne (see abstract). Sclareolide is taught in combination with other ingredients (see col. 5, line 6 through col. 7, line 12). Subbiah teaches that sclareolide has antimicrobial activity that is useful in the treatment of acne (see col. 4, lines 45-65).

Ichinose teaches that white birch extracts are known anti-inflammatory agents (see col. 5, lines 4-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of Ribier '166 by the addition of sclareolide for its anti-acne properties as taught by Subbiah and by the addition of white birch extract for its anti-inflammatory properties as taught by Ichinose. The motivation for the modification comes from the benefit of such properties in formulating cosmetic

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compositions. The missing ingredients have art-recognized suitability for the intended purpose of formulating cosmetic compositions. The selection of a known material based on its suitability for its intended use has been determined to be *prima facie* obvious. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945); *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960); and MPEP 2144.07.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on alt. Mondays and Tuesday to Friday (9am-6:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


Michael A. Willis
Examiner
Art Unit 1617

maw
November 2, 2002


SREENI PADMANABHAN
PRIMARY EXAMINER 11/2/02